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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,136	12/23/2002	Wolfgang Heimberg	REN-13087/5800US	2520

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MH2 TECHNOLOGY LAW GROUP, LLP
1951 KIDWELL DRIVE
SUITE 550
TYSONS CORNER, VA 22182

EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,136	Applicant(s) HEIMBERG ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/15/2008 and 07/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed 06/03/2008 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 25 recites the segments of the reaction vessel receiving element being insulated from each other with a thermal insulator inserted in a gap,-between adjacent segments. Although the originally filed claim 5 (currently canceled) provided support for this limitation, it is not recited in the specification. The specification supports non-conductive ties / webs used for connecting the segments, but not thermal insulators providing insulation between the segments, as currently recited. Therefore, the instant disclosure fails to provide proper antecedent basis for the claimed subject matter.

Claim Rejections - 35 USC § 112

4. The 35 U.S.C. 112, first paragraph, rejection of claim 25 is withdrawn, in view of the latest clarifications provided by the Applicant.

5. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 remain rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The currently amended claim 19 recites “two or more devices for heating and cooling_the reaction vessel receiving element, wherein each device corresponds to *only* one segment”. It is unclear whether or not the intended heating and cooling devices must correspond to the very same segment.

Referring to claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56, it remains unclear whether or not any actuators are intended, to provide for the “heating / cooling devices being “actuated independently of one another to set and maintain different temperatures in two adjacent segments wherein the system provides different temperatures to the segments during a temperature cycle to optimize the parameters for PCR”. It is also not clear, with respect to claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-55, whether or not the intended apparatus includes a controller.

Additionally, it is unclear whether or not the recitation of the reaction vessel receiving element being configured for holding specifically a standard micro-titer plate, means any limitations to the dimensions of the receiving element.

With respect to claim 25, it remains unclear how the segments can be insulated from each other by inserting a thermal insulator into an air filled gap between the segments, since inserting such insulators would only deteriorate the thermal insulation, because the thermal conductivity of practically all known solid insulating materials is higher than that of the air.

Claim Rejections - 35 USC § 103

6. Claims 19, 21-23, 25, 27, 35, 37, 41, 43, 49 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 5601141) in view of Potter et al. (US 5819842).

As was shown previously, with respect to claims 19, 21-22, 35, 37, 41 and 43, Gordon discloses a modular thermo-cycler that carries samples through one or more predetermined temperature profiles and comprises a base and an array of modules ['segments'] mounted on the base. The modules are "substantially isolated from one another, thermally and functionally... The module has a temperature sensor adjacent the samples, an electrical resistance heating element, and a circulating fluid heat exchanger for step cooling...The modules are preferably formed in three layers--a sample plate ['thin-walled reaction vessel holders'- see 14a of Figure 4], a heater plate, and a cooling plate ['devices for heating and cooling', see elements 14 b-c of Figure 4] adjacent to a manifold... The sample plate is preferably replaceably secured at the upper surface of the module on the heating plate... The sample plate is adapted to receive a standard

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micro-titration plate, or other labware, in a close, heat-transmitting engagement

The heater plate and cooling plate may be formed integrally, thus forming a device for heating and cooling a module / segmen - (see Abstract; Col.1, line 5; Col.2, lines 10-40). Figure 6 shows channel 46 filled with heat dissipating fluid ['temperature equalization element'].

Although the modules of Gordon are disclosed as being adapted to receive a standard micro-titration plate each (rather than a single standard plate altogether), they are definitely capable of supporting a single standard plate. For example, any two adjacent modules 14 (see Figure 14), or any four adjacent modules forming a 2x2 array can support a single standard plate which would occupy a portion of each module, each module individually controlling a corresponding portion of the plate. It would have been also within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Gordon such that it would provide individual and independent heating / cooling of separate portions of a single standard micro-titer plate, in order to increase the scope of scalability and applicability of the apparatus, and, consequently, to enhance its commercial / marketing value, the thermo cyclers configured to independently control the portions of a single plate being well known in the art. For example, Potter et al. disclose a device for "independent control of multiple samples which are in close proximity" (Abstract). The device comprises, as shown in Figures 1-3, a multi-well sample plate 10 having wells 13, the temperature within each well being independently controlled by heat controlling segments 21 of sample vessel receiving structure 20. Potter also

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discloses Peltier thermoelectric devices as possible heat controlling elements (Col.2, line 43).

With respect to claims 23 and 25, Gordon teaches that “the modules are spaced laterally, from one another [‘decoupled by means of air gaps’] which in combination with forming the base of the insulator, provides a good degree of thermal isolation of each module” (Col.3, lines 40-45). It would have been also within the ordinary skill of an artisan at the time the invention was made to have modified the thermal conductivity of the gaps (depending on particular goals of thermo-cycling) by filling them with materials having different thermal conductivity characteristics (including thermal insulators), in order to achieve more flexible and precise control over temperature conditions in the apparatus of Gordon.

Regarding claim 27, Gordon refers to the use of Peltier elements for heating or cooling as being well known in the art in column 1, lines 30-35.

With respect to claims 49, and 53-55, these are limitations to the process of using the device, which are not attributed patentable weight in a claim to the apparatus. It would appear that the apparatus of Gordon et al. is capable of operating in this manner.

Referring to claim 56, Gordon teaches that a controller “regulates the electrical current and cooling fluid flows to each module in response to a signal from a temperature sensing element associated with each module”(Col.2, lines 15-20; Col.4, line 45; Col.5, line 55).

Double Patenting

7. Claims 19 and 41 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending Application 11/470463, over claim 18 of co-pending Application 11/450442, over claim 18 of co-pending Application 11/651986, and over claim 26 of co-pending Application 11/651985. See the appropriate paragraphs of the 06/12/2008 Office Action.

Response to Arguments

8. Applicant's arguments filed 06/03/2008 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that Gordon et al. are deficient in teaching a segmented receiving element configured to receive one standard micro-titer plate. Examiner maintains that it would have been within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Gordon such as to provide individual and independent heating / cooling of separate portions of a single standard micro-titer plate, in order to increase the scope of scalability and applicability of the apparatus, and, consequently, to enhance its commercial / marketing value. See the discussion above.

Applicant further argues that Gordon does not teach "each (heating/cooling) device corresponding to one segment" of the receiving

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element.” Examiner notes that Gordon teaches each module [‘segment’] having a heater plate, and a cooling plate (elements 14 b and c, as shown in Figure 4).

Applicant argues that, “while Gordon et al. may be “capable” of supporting some type of non-standard_plate, a standard microtiter plate is only and specifically disclosed as being supported by a single module”. Examiner emphasizes that the microtiter plate is not positively recited in the instant claims as part of the claimed invention, and, therefore, it is not accorded patentable weight.

Applicant seems to agree that “Potter et al. disclose a device for independent control of multiple samples, as well as Peltier thermoelectric devices as possible heat controlling elements. Applicant , however, argues that, “even assuming, arguendo, that Potter et al. disclose these features, ...the “cooling” in Potter et al. is with a cold block 25 which spans an entirety of the sample plate 10 rather than corresponding to one segment as claimed”. Examiner notes that Potter was cited to support the concept of modular temperature control within a single plate, which Potter does teach. Examiner also notes that the heat dissipating block 25 does not preclude modular temperature control via individually actuated heat elements 21, which are also thermally shielded from block 25 by discs 23 of higher thermal resistance.

Finally, Applicant argues that Potter et al. “fail to disclose a standard microtiter plate as claimed”. Examiner would like to remind that the microtiter plate is not positively recited in the instant claims, and, therefore, is not accorded patentable weight. Also, as noted above, Potter was cited to support the concept

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of modular temperature control within a single plate, which Potter does teach, as was shown above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462.

The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797